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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/506,807	03/04/2005	Haruki Mizukami	136033	5414

25944 7590 01/05/2009

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EXAMINER	
NGUYEN, BAO THUY L	

ART UNIT	PAPER NUMBER
1641	

MAIL DATE	DELIVERY MODE
01/05/2009	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/506,807	MIZUKAMI, HARUKI	
	Examiner	Art Unit	
	Bao-Thuy L. Nguyen	1641	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *06 October 2008*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1,4-8 and 17-31* is/are pending in the application.

4a) Of the above claim(s) *22-31* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1,4-8 and 17-21* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

1. The Request for Reconsideration dated 06 October 2008 has been received.

2. Claims 1, 4-8 and 17-21 are pending.

Claim Rejections - 35 USC § 103

3. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

4. Claims 1, 4-8 and 17-21 are rejected under 35 U.S.C. 103(a) as being unpatentable over Cole et al (US 5,141,850) in view of Fitzpatrick et al (US 5,451,504) and Durst et al (US 5,789,154).

Cole discloses a device and method comprising a water-dispersible labeled component that comprises the coupling product of a first immunologically reaction substance and a detectable species; providing a water-dispersible capturable component that comprises the coupling product of a capturable species and a second immunologically reactive substance; providing a capturable component that is localized at a detection zone in a porous carrier material and which comprises a capturing substance capable of interaction with a reaction product containing the capturable species to thereby capture and collect the product at the detection zone. See column 2, lines 24-62. Cole discloses that the labeled component is initially a dry, reconstitutable, water-dispersible and diffusible and is reconstituted by the sample liquid. See column 2, line 63 through column 3, line 2.

Cole differs from the instant invention in failing to teach a zone to capture unbound label products. Cole also fails to teach the detection of pollutants such as PCB or dioxins.

Fitzpatrick, however, discloses a device similar to those of Cole. Fitzpatrick further teaches the capture of unbound labeled reagents. See column 1, line 57-68.

And Durst teaches that small analytes such as dioxin and PCBs are easily measurable using conventional techniques. See claim 13.

Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to modify the device taught by Cole to include a trap zone to capture unbound labeled reagents such as taught by Fitzpatrick because such modification would provide the advantage of a device that yields a detectable results in the case of a negative test leading to more accuracy in assay interpretation.

A skilled artisan would have had a reasonable expectation of success in assembling the device of Cole as modified by Fitzpatrick in a detection set, i.e. kit, such as taught by Cole because kits provide the advantages of economy and convenience and are well-known in the art.

It also would have been obvious to one of ordinary skill the art at the time the invention was made to use the device of Cole as modified by Fitzpatrick to measure analytes such those taught by Durst because Cole teaches that their device is appropriate for the detection of a wide variety of analytes with the appropriate selection of reagents.

5. Claims 1, 4-8 and 17-21 are rejected under 35 U.S.C. 103(a) as being unpatentable over Cole et al (US 5,141,850) in view of Fitzpatrick et al (US 5,451,504) and Neuman (US 5,057,275).

See the discussion of Cole and Fitzpatrick above. These references differ from the instant claims in failing to specifically teach reagents for dioxin or PCBs.

Neuman teaches that environmental contaminants such as dioxins and PCBs are easily detected using antibodies specific therefor.

Thus, it would have been obvious to one of ordinary skill in the art at the time the invention was made to use the device of Cole as modified by Fitzpatrick to measure analytes such as those taught by Newman because Cole teaches that their device is appropriate for the detection of a wide variety of analytes with the appropriate selection of reagents.

Response to Arguments

6. Applicant's arguments filed 06 October 2008 have been fully considered but they are not persuasive.

Applicant argues that none of the cited references teaches or renders obvious every claimed feature of independent claim 1. Specifically, "a reaction product contact section" where the reaction product is produced by "reacting a test sample with a label product containing an antibody specific for dioxins and PCB" and an unbound label product capture section.

In response to applicant's arguments against the references individually, one cannot show nonobviousness by attacking references individually where the rejections are based on combinations of references. See *In re Keller*, 642 F.2d 413, 208 USPQ 871 (CCPA 1981); *In re Merck & Co.,* 800 F.2d 1091, 231 USPQ 375 (Fed. Cir. 1986).

As stated above and in the previous office action, Cole teaches a device comprising a "reaction product contact section", see column 2, lines 34-62, where Cole recites a detection zone

in a porous carrier material. Cole also teaches a water-dispersible labeled component that comprises a label and a binding partner. The reaction product taught by Cole does not have an antibody specific for dioxins and PCB, however, this is taught by Durst. Durst teaches that analytes such as dioxin and PCBs can be detected using antibodies. Durst also teaches labeled antibodies specific for the analyte. See column 3, lines 43-55. Clearly, Cole in view of Durst makes obvious an anti-dioxin or anti-PCB antibodies that is labeled. Cole in view of Durst also makes obvious a reaction product produced by contacting the test sample with the labeled antibodies. And finally, the unbound label product capture section is taught by Fitzpatrick. See column 1, lines 57-68.

The argument that neither Cole nor Fitzpatrick discloses a test sample which is reacted in advance outside of a chromatography device is not persuasive. Cole clearly recites that the detection reactions occur in a liquid phase with all components in a freely mobile state. Cole teaches that this improves the efficiency and rapidity of the invention. See column 2, lines 23-30. Fitzpatrick is cited for their disclosure that a device with capture zone for capturing unbound labeled reagents is well known and conventional in the art. Such a device also provides the advantage of being able to yield a detectable signal even in the case of a negative test leading to more accuracy in assay interpretation.

The argument that Neuman does not remedy the deficiencies of Cole and Fitzpatrick because Neuman does not teach a reaction product contact section, a reaction product produced by contacting the sample with a labeled anti-dioxin or anti-PBC antibody and an unbound label product capture section is not persuasive.

As stated above, Cole teaches the device and method substantially as claimed including a reaction product contact section. Fitzpatrick teaches the unbound label product capture section and Neuman teaches that dioxins and PCBs are easily detecting using antibodies. Clearly, Cole in view of Fitzpatrick and Neuman teaches the invention in its entirety.

Conclusion

7. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

8. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Bao-Thuy L. Nguyen whose telephone number is (571) 272-0824. The examiner can normally be reached on Monday -- Thursday from 9:00 a.m. - 3:00 p.m.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Mark Shibuya can be reached on (571) 272-0806. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Bao-Thuy L. Nguyen/
Primary Examiner, Art Unit 1641
January 4, 2009